REMARKS

The above amendments are in response to the Office Action dated March 4, 2010. The deadline for response has been extended one month to July 4, 2010, by payment of appropriate government fees for a one month extension of time. Claims 1-17 are pending for consideration. By this amendment, paragraphs [0071] and [0072] of the specification and claims 1, 2, 7, 12, 14-16 are amended. Claims 4, 5, 10, and 17 are cancelled. Support for the amendment can be found in the specification and claims as originally filed. For example, support for the amendments to claims 1 and 2 can be found in the specification at least in paragraphs [0012], [0015], [0017], [0028], [0029], and [0031], and cancelled claims 4 and 5. Support for claim 7 can be found in cancelled claim 10. Further, the claims have been amended to correct informalities and clarify the scope of the claimed invention. Applicants submit that no new matter has been added and respectfully request reconsideration and withdrawal of the pending rejections.

I. Objections to the Specification

The specification is objected to because abbreviations are used in the specification without being spelled out. In response, Applicants have amended paragraphs [0071] and [0072] to indicate that CMD is CarboxyMethylDextran, that FA is fatty acid and, as the Examiner acknowledged, that DMF is dimethylformamide. Applicants believe the amendment is sufficient to define these abbreviations wherever they appear.

II. Claim Objections

Claim 16 is objected to because it contains two different types of symbols, and the Examiner suggests that those "*" items that only relate to "the pain and/or pruritis induced by" be further indented. In response, applicants have amended claim 16 with further indentation, as requested.

III. Double Patenting

Claims 1-9, 12, 14 and 16 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 2-6 of U.S. Patent No. 6,689,741. In response, applicants herewith submit a Terminal Disclaimer.

Claims 1-9, 12, 14 and 16 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 70 of copending Application No. 10/695,574. In response, applicants herewith submit a Terminal Disclaimer.

Claims 1-9, 12, 14 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 12/212,093. In response, applicants herewith submit a Terminal Disclaimer.

IV. Claim Rejections – 35 USC § 112

Claims 1-9, 12, 14 and 16 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states in paragraph 9 that the particular polymers that were synthesized using the procedure set forth in Example 1, which do not have any intervening groups, do meet the written description requirement and that those examples are limited to glucose. In response, applicants traverse this rejection. However, in further response, applicants herewith amend claim 1 to recite that A is glucose. This rejection is therefore rendered moot with this amendment.

Claims 7 and 9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, only those Z groups which were explicitly mentioned in the specification meet the written description provision. In response, applicants respectfully traverse this rejection.

However, in further response, applicants point out that claim 9 depends from claim 7 and that claim 7 has been herewith amended to introduce the limitations from claim 10, which recites Z groups listed in the specification and which is not under rejection. Withdrawal of this rejection is therefore respectfully requested.

Claims 1-9 are rejected under 35 U.S.C. § 112, first paragraph, for the alleged reason that the specification, while being enabling for treating pain associated with a tissue, does not reasonably provide enablement for treating or preventing all discomfort, unpleasant symptoms and irritation and preventing pain associated with a tissue. Applicants respectfully traverse this rejection. However, in further response, applicants amend claim 1 to recite "treating pain associated with a tissue." Applicants accordingly respectfully request withdrawal of this rejection.

Claims 1-9, 12, 14 and 16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner is unclear about what structural arrangements are required for the resulting polymers because, according to the Examiner, formula (I) does not allow Y to be attached to A but to X. Applicants have amended claim to recite that the possible formulas are: AaXxYy, AaXx, AaYy, and AaYyXx. As noted above, support for this amendment can be found in the specification at least in paragraphs [0028] and [0029]. Applicants accordingly respectfully request withdrawal of this rejection.

Additionally, the Examiner states that "R" is defined as being "an aliphatic chain... which may contain one or more aromatic rings" but as defined in the art, an aliphatic chain does not contain any aromatic rings. Applicants assert that this rejection is moot in view of the amendment to claim 1.

The Examiner also states that it is unclear what "x" and "y" represents as the claims are drawn to a product and not a process of making a product and thus, there are no rates involved to be a "rate of substitution". Additionally, the Examiner states that the basis upon which the percentages of these rates of substitution is calculated in

claims 4, 5 and 8 is unclear as no baseline rate has been described. The Examiner requests clarification regarding these points. In response, applicants assert that the term "rate" may be confusing. It is not intended to indicate a "process" but rather the percentage of substitution of A by either X or Y. Applicants direct the Examiner's attention to paragraph [0020] which explains this concept in detail.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for depending from Claim 1, wherein A is a monomer. According to the Examiner, claim 2, which intends to further define A, recites polymers such as proteins and nucleic acids. Applicants note that claim 1 has been amended to clarify the scope of the claims and to recite that A "comprises a monomer that is glucose." Applicants note that A comprises glucose, and therefore can additionally comprise other monomers, such as the monomers listed in claim 2. For example, as noted in paragraph [0031] of the specification, A can comprise a repeated saccharide that has several elements. Withdrawal of this rejection is respectfully requested.

Claim 3 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting "approximately". Applicants assert that this rejection is rendered moot in view of the amendment to claim 3. Withdrawal of this rejection is therefore respectfully requested.

Claims 12, 14 and 16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for reciting intended uses. In response, applicants have amended the rejected claims to remove the allegedly offending language and also to clarify the remaining claim language. Withdrawal of this rejection is respectfully requested.

V. Claim Rejections – 35 U.S.C. § 102

Claims 1-9, 12, 14 and 16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Barritault et al. (US 2001/0021758) ("Barritault"). Applicants respectfully traverse this rejection as it may apply to the amended claims.

Barritault does not teach using the biocompatible polymer of the invention to treat pain. More specifically, Barritault does not teach a method of treating pain associated with a tissue in a human, comprising contacting the tissue with a pharmaceutical, dermatological or cosmetic composition or a medical device comprising the claimed biocompatible polymer in an amount effective to treat pain, wherein the method does not treat the cause of the pain. The Examiner appears to conclude that because Barritault teaches applying the claimed biocompatible polymer to tissue in paragraph [0126] and in a rat model in Example 8, these teachings inherently discloses the treatment of pain in such tissue. Applicants disagree.

First, with regard to Example 8, Barritault shows the creation of a defect in the flat bone of a rat. This defect is then filled with a collagen buffer that is impregnated with biocompatible polymers. The results show an indication of osseous regeneration. The purpose of this experiment is to determine whether the tested compounds stimulate bone regeneration. This experiment is not concerned with testing pain. Nothing in this Example, or in any other Example, teaches or suggests that the amount of the biocompatible polymer impregnated in the collagen would have treated pain or that there was, in fact, any pain to be treated in this animal model. Claim 1 requires that the amount of the biocompatible polymer is an amount that is effective to treat pain. Example 8 fails to teach this element. In the absence of a teaching of this element, a rejection under § 102 is defective. Additionally, it is clear that Example 8 does not teach "a dermatological or cosmetic composition or a medical device" comprising the claimed biocompatible polymer. Arguably, Example 8 also fails to disclose a pharmaceutical containing the biocompatible polymer of the invention. Example 8 discloses a narrow experiment done with an animal model to test the regenerative activity of the compounds, *per se*. It does not test any specific pharmaceutical formulation. Thus, for these deficiencies as well, applicants argue that Barritault is an improper reference under § 102. These arguments are applicable to other animal model experiments set forth in other Examples disclosed in Barritault.

The Examiner also has said that with regard to claims 7 and 9, the cited polymers, z has a value of 0, so that no Z substituent is present in the polymer. Applicants argue that the deficiencies pointed out above with regard to claim 1, apply to claims 7 and 9 as well and claims 7 and 9 depend from claim 1. With regard to claims 12, 14 and 16, the Examiner states that the language indicating an "intended use" would render Barritault anticipatory because the polymers in question are the same. Although applicants traverse this rejection for reasons set forth above, this rejection is rendered moot in view of the amendment to the rejected claims.

VI. Claim Rejections – 35 U.S.C. § 103

Claims 1-9, 12, 14 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Barritault et al. (US 6,689,741) ("Barritault II") as evidenced by Hunter et al. (US 2003/157161) ("Hunter"). Applicants respectfully point out that Barritault II (US 6,689,741) and Barritault (US 2001/0021758) are the same document, with Barritault II being the patent that matured from Barritault. The Examiner's position appears to be that because Barritault II (column 11, line 38) teaches using the claimed polymers for treatment of arthritis and because arthritis is associated with pain, as taught by Hunter, it would have been obvious at the time of the invention to contact inflamed, arthritic tissue with the polymer of Barritault II for purposes of treating pain. Applicants respectfully traverse this rejection.

The primary disclosure upon which the Examiner's rejection is based, is the following statement: "In the treatment of inflammatory diseases such as arthritis."

This statement is part of a long list of therapeutic effects thought to result from RGTA's ability to protect or stabilize the enzymatic activities of superoxide dismutase or SOD. Applicants argue that nothing in this statement or the long list of other therapeutic effects in the cited primary reference, would have suggested to the skilled artisan that the polymers of the invention could be used to treat pain. The Examiner's rejection is based simply upon the acknowledgement that arthritis and pain are

sometimes found together. That is, according to the Examiner, by treating the underlying disorder, one would also be treating the side-effect of this disorder. Applicants believe this logic is flawed and would not have appealed to one of skill in the art at the time of the invention. If a compound was found to be effective against baldness, would one of skill in the art assume that the same compound would treat sunburns because baldness and sunburn are often found together? Applicants argue that they would not, and similarly would not have assumed that the claimed polymers could be used to treat pain based upon a teaching that the polymers of the invention stimulate tissue regeneration and can be used to treat arthritis and that arthritis is painful. Applicants also point out that the intent of the invention is not to treat the disorder that is the cause of the pain, as stated in the specification at paragraph [0058], but to treat the pain, per se.

Although applicants vigorously argue that the Examiner has not presented a *prima facie* case of obviousness, applicants also point out that the degree to which the polymers of the invention treat pain was unexpected. Specifically, applicants direct the Examiner's attention to 24 examples in the present specification describing the treatment of pain, caused by a wide variety of things, with the use of specific polymers. These Examples demonstrate that the biocompatible polymers of the present invention have a greater effect on pain when compared to the more powerful known analgesic, such as Diantalvique and/or morphine, regardless of what causes the pain (see for example, Example II of the specification.) Moreover, the examples clearly demonstrate that the treatment of pain using the polymers of the invention is faster than treatment with known compounds (see Example II of the specification.)

Applicants argue that the broad applicability and speed and efficacy of the invention would have been unexpected, and therefore, non-obvious over the prior art. In view of the above arguments and amendment, applicants respectfully request the Examiner to withdraw this § 103 rejection over Barritault II and Hunter.

Claims 1-9, 12, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barritault II, as evidenced by Hunter, as applied to claims 1-9, 12, 14 and 16 above, and further in view of Deibig et al. (US 4,451,452) ("Deibig"). The Examiner states that Barritault II does not teach polymers substituted with acetate groups as Z. Deibig is cited for disclosing that physical properties of water soluble polymers such as dextran can be modified by incomplete esterification with mono- or di-carboxylic acid that make the polymers water-insoluble but still water-swellable. According to the Examiner, it would have been obvious at the time of the invention to substitute the carboxymethylated and O-sulphonated biocompatible polymers of Barritault II with acetate groups. Applicants traverse this rejection for reasons set forth above with regard to the Examiner's rejection over Barritault II combined with Hunter. Deibig does not cure the deficiencies pointed out above.

But Deibig is deficient for other reasons. Deibig only discloses a polymer that can be used as a support for active molecules. It does not disclose or suggest that polymer AXY with a Z group as defined in the claims would have better properties. Moreover, the compounds disclosed in Deibig are different from those of the present invention and one could not have predicted that a same chemical group or substituent would have had the same effect. In view of the shortcomings of Deibig alone and in combination with Barritault II and Hunter, applicants respectfully request the Examiner to withdraw this rejection.

CONCLUSION

In view of the above amendment, arguments and Terminal Disclaimers, applicants believe this application is in condition for allowance. Should the Examiner believe that anything further is necessary in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

Applicants believe no further fees are due with this response. In the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 01-2300 (referencing docket number 021305.00321) from which the undersigned is authorized to draw.

Dated: July 2, 2010

Respectfully submitted,

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